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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/795,870

03/08/2004

Ryuichi Ugajin

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12/08/2005

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EXAMINER

JACKSON JR, JEROME

ART UNIT

PAPER NUMBER

2815

DATE MAILED: 12/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/795,870

Applicant(s)

UGAJIN ET AL.

Examiner

Jerome Jackson Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 80-242 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 80-242 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/980314.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/8/04</u> . | 6) <input type="checkbox"/> Other: ____ |

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 80-242 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. There is no enablement for any claim, for example, as in claim 80 "multiply twisted helix having a hierarchical structure in which a linear structure as an element of a spiral structure is made of thinner spiral structures, characterized in: at least two layers of spiral structures being bonded in at least one site". There are no examples of any structure as stated above that applicant has made or could make. These claims are vague generalities of some helical structure and there is no way to ascertain how to make such structure without undue experimentation. There are no examples in the specification of any exact structure, no exact blueprint of how to make such a structure, no way to determine what such a structure is, and no way to begin to even attempt to make and determine what exactly applicant has and is claiming. Applicant needs to show by experimental evidence exactly what structure he is claiming, how to make it, and show atom by atom exactly what the structure is. There is no enablement here. Mere reference that DNA molecules possess similar structure does not enable applicant's claims, does not distinguish applicant's claims over known DNA structure, and does not show how one of ordinary skill would make and use applicant's purported

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invention. As can be best determined applicant's claims vaguely delineate some hypothetical helical structure that may be possible to simulate on a computer. There is no evidence that applicant has or can make such helical structure even if one of ordinary skill could possibly understand what applicant is actually claiming.

Even if one assumes that applicant's claimed structure could possibly be made by applicant (which is not here) applicant would need to show how his structure defines over ordinary chromosomal genetic material which comprises multiply twisted helical structure bonded in many places, twisted three dimensionally, and apparently meets all the claim limitations. None of the structural or functional language "fluctuation in bonding site", "appears in a predetermined pitch", "controlled by controlling the bonding site", etc. structurally distinguishes over a genetic chromosome.

Applicant has the burden of proving that he can make the claimed structure:

The burden of showing what that exact structure is:

The burden of showing how it distinguishes over the prior art, i.e. chromosomal material:

The burden of showing atom by atom exactly what the structure is as it cannot be determined from the bare description of the original disclosure:

The burden of showing that the claimed structure can be made with the description given.

The MPEP at 2164.01(a) describes factors regarding "undue experimentation" in a rejection under 35 USC 112 1st paragraph as we have here. In applicant's case all the factors are pertinent, but especially (B), (F), (G), and (H). The nature of applicant's

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invention (B) involving computer simulated helical structure similar to DNA requires not only that applicant show exactly how to make the invention but also how it distinguishes over DNA structure. Factor (F) regarding the amount of direction provided by the applicant requires again that applicant particularly point out and distinguish over DNA structure and show exactly what the structure is atom by atom as "twisted helical structure" is complex and the exact structure atom by atom should be disclosed to prove the invention can be made without "undue experimentation". Factor (G) the existence of working examples requires that applicant show working examples as the claimed "twisted helical structure" is complex and applicant has not shown any examples but only vaguely referred to DNA. Factor (H) regarding the quantity of experimentation needed to make the invention requires that applicant show exactly how to make the claimed structure atom by atom as there are no working examples given or exact methods stated to make and use the invention which by its complicated "twisted helical" structure can be determined, and there is no evidence that anyone else has made such claimed structure which is apparently similar to DNA.

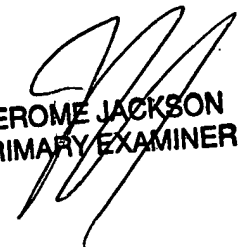
Computer simulations are not acceptable as enabling here for the reasons stated above and further because the figures and description do not show atom by atom what even the computer simulations are. It is not even clear what the helix in figure 2 comprises atom by atom. The disclosure does not even state exactly what the material of the helix exactly is. The disclosure is non-enabling.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerome Jackson Jr. whose telephone number is 571-272-1730. The examiner can normally be reached on M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tom Thomas can be reached on 571-272-1664. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

jj


JEROME JACKSON
PRIMARY EXAMINER